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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Yamamoto, et. al.

Examiner: NYA

Serial No:

10/797,903

Group Art Unit: 3612

Filing Date:

March 10, 2004

Priority Appln. No.: JP 2003-062823; filed: March 10, 2003

JP 2003-302803; filed: August 27, 2003

Title:

c-KIT KINASE INHIBITOR

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

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I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O<sub>n</sub>Box 1450, Alexandria, VA 22313-1450

March 3, 2006

Date

Signature

Mary Wilson

Typed or Printed Name of person signing certificate

## TRANSMITTAL LETTER

Enclosed herewith please find the documents listed below:

- 1. Copy of the English Translation of the International Preliminary Report on Patentability (Chapter 1) issued in PCT/JP2004/003087 (6 pages); and
- 2. Return Post Card.

Dated: March 3, 2006

Respectfully submitted,

Charles E. Lyon, D.Phil.

Agent for Applicant Reg. No.: 56 630

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### From the INTERNATIONAL BUREAU

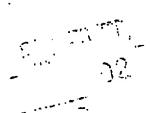
# PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)

(PCT Rules 44bis.3(c) and 72.2)

To:

HASEGAWA, Yoshiki Soei Patent and Law Firm Ginza First Bldg. 10-6, Ginza 1-chome Chuo-ku, Tokyo 1040061 JAPON



Date of mailing (day/month/year) 23 February 2006 (23.02.2006)		· · · · · · · · · · · · · · · · · · ·	
Applicant's or agent's file reference FP04-0096-00		IMPORTANT NOTIFICATION	
International application No. PCT/JP2004/003087		International filing date (day/month/year) 10 March 2004 (10.03.2004)	
Applicant	EISAI CO.	., LTD. et al	

1.	Transmittal	of the	translation	to th	e appucant	

<b>V</b>	The International Bureau transmits herewith a copy of the English translation of the international preliminary report patentability (Chapter 1).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

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The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsinule No.+41 22 338 70 10



Facsimile No.+41 22 740 14 35

# SOEI PATENT & LAW PATENT COOPERATION TREATY

# **PCT**

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter 1 of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP04-0096-00	FOR FURTHER ACTION	Priority date (day/month/year) 10 March 2003 (10.03.2003)	
International application No. PCT/JP2004/003087	International filing date (day/moruh/year) 10 March 2004 (10.03.2004)		
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant EISAI CO., LTD.			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis. 1(a).				
2.	This REPORT consists of a total				
	In the attached sheets, any refere to the international preliminary i	ence to the written opinion of the report on patentability (Chapter	ne International Searching Authority should be read as a reference  [I] instead.		
3.	This report contains indications	relating to the following items:			
	Box No. I	Basis of the report			
	Box No. II	Priority			
	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability			
	Box No. IV	Lack of unity of invention			
	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
	Box No. VI	Certain documents cited			
	Box No. VII	Certain defects in the intern	national application		
	Box No. VM	Certain observations on the international application			
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).				
<u></u>					
	Date of issuance of this report 13 February 2006 (13.02.2006)				
	The International Bur 34, chemin des Co	olombettes	Authorized officer  Masashi Honda		
Facsimile No. +41 22 740 14 35 Telephone No.		Telephone No. +41 22 338 70 10			

Form PCT/IB/373 (January 2004)

# PATENT COOPERATION TREATY

From the INTERNATIONAL	SEARCHING AUTHOR	ITY		ans.	
To:				PCT PCT	
				RITTEN OPINION OF THE IONAL SEARCHING AUTHORITY	
		·		(PCT Rule 43bis.1)	
			Date of mailing (day month year)		
Applicant's or agent's	s file reference		FOR FURTHER.	ACTION	
FP04-0096	5-00			See paragraph 2 below	
International applicate PCT/JP200		International filing date (	day month year)	Priority date (day month year) 10.03.2003	
	Classification (IPC) or both	national classification and	d IPC		
Applicant EISAI CO.	, LTD.				
1. This opinion	on contains indications rela	ting to the following items	s:		
В₀	x No. I Basis of the	opinion			
B∞	x No. II Priority				
Bo	x No. III Non-establi	shment of opinion with re	regard to novelty, inventive step and industrial applicability		
Во	x No. IV Lack of uni	ty of invention			
	x No. V Reasoned st applicability	latement under Rule 43 bis. y, citations and explanation	.1(a)(i) with regard to ns supporting such stat	novelty, inventive step or industrial tement	
В Во	x No. VI Certain doc	uments cited			
☐ Bo	x No. VII Certain defe	ects in the international ap	plication	•	
Во	ox No. VIII Certain obs	ervations on the internation	nal application		
If a dema Internation than this o this Interna If this opin written rep PCTASA	nal Preliminary Examining one to be the IPEA and the ational Searching Authority mion is, as provided above ply together, where approached or before the expiration	Authority ("IPEA") except chosen IPEA has notified will not be so considered to be a written printe, with amendments, not 22 months from the printer than the p	ot that this does not ap If the International Bur I. en opinion of the IPE. before the expiration	ill be considered to be a written opinion of the oply where the applicant chooses an Authority other reau under Rule 66.1bis(b) that written opinions of A the applicant is invited to submit to the IPEA an of 3 months from the date of mailing of Form respires later.	
For further	r options, see Form PCT/15	SA/220.			
3. For further	r details, see notes to Form	РСТЛЅА/220.			
			Authorized officer		
Name and mailing a	ddress of the ISA/JP		-Anthonized officer		
Facsimile No.			Telephone No.		

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/JP2004/003087

Во	x No. I	Basis of this opinion
1.	With filed	regard to the language, this opinion has been established on the basis of the international application in the language in which it was Lunless otherwise indicated under this item.
		This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under
	•	Rule 12.3 and 23.1(b)).
2.	With inve	h regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed ention, this opinion has been established on the basis of:
	a.	type of material
		a sequence listing
		table(s) related to the sequence listing
	b.	format of material
		in written format
		in computer readable form
	c.	time of filing/furnishing
		contained in the international application as filed.
		filed together with the international application in computer readable form.
		furnished subsequently to this Authority for the purposes of search.
3.		In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4.	Ad	ditional comments:
L		

# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/003087

		oned statement under Rule 43 bis.1(a)(i) with regard to novelry, inventive step or industrial applications; ons and explanations supporting such statement		- maustriai applicaemty;
1.	Statement			
,	Novelty (N)	Claims		YES
i I		Claims	1-15	NO NO
	Inventive step (IS)	Claims		YES
		Claims	1-15	NO NO
	Industrial applicability	(IA) Claims	1-15	YES
		Claims		NO NO

2. Citations and explanations:

(Documents)

- 1. WO 02/032872 A1 (Eizai Co., Ltd.), 25 April, 2002 (25.04.02)
- 2. WO 00/43366 A1 (KIRIN BREWERY CO.,LTD.), 27 July, 2000, (27.07.00)
- 3. WO 2004/039782 A1 (KIRIN BREWERY CO.,LTD.), 13 May, 2004 (13.05.04)

(Explanations)

## Concerning claims 1-10 and 12-14:

The inventions disclosed in claims 1-10 and 12-14 do not appear to be novel or to involve an inventive step on account of document 1 cited in the ISR. Document 1 discloses that compounds represented by the general formula I described in claim 1 of the present application are effective as an anticancer agent, an angioma remedy, a cancer innidation inhibitor and a drug for curing inflammatory affection caused by delayed irritation. Also, it is disclosed in the specification of the present application that the c-Kit kinase inhibitor of the present application is effective as a drug for curing various tumors, allergy and asthma, so that the inventions disclosed in claims 1-10 and 12-14 cannot be held to be different from the inventions disclosures in document 1.

Furthermore, the inventions disclosed in claims 1-10 and 12-14 do not appear to involve an inventive step on account of document 2 cited in the ISR. Document 2 discloses that compounds with similar structures as those of compounds represented by the general formula 1 described in claim 1 of the present application are effective as an anticancer agent, etc. Also, it is usual practices in the field of medicine to modify structures of pharmacologically active compounds as one thinks fit, so that it is obvious for a person skilled in the art to examine anticancer activity of compounds disclosed in document 2 by changing, as one thinks fit, a substituent in the 6<sup>th</sup> or 7<sup>th</sup> position etc. on the quinoline ring of which various alternatives are described.

### Concerning claims 11 and 15:

The inventions disclosed in claims 11 and 15 do not appear to be novel or to involve an inventive step on account of document 1 cited in the ISR. Document 1 discloses that compounds represented by the general formula I described in claim 1 of the present application are effective as a drug for curing inflammatory affections caused by delayed irritation and other drugs, and it can be considered that allergy and asthma, etc. correspond to inflammatory affections caused by delayed irritation.

#### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/JP2004/003087

Box	No. VI Certain documents cited			
1.	Certain published documents (Rule 43bis.1 and 7	0.10)		
	Application No. Patent No.	Publication date (day. month year)	Filing date (day month year)	Priority date (valid claim) (day: month year)
	WO 2004/039782 AL [EX]	13.05.2004	29.10.2003	29.10.2002
2.	Non-written disclosures (Rule 43bis.1 and 70.9)			
	Kind of non-written disclosure	Date of non-written d	lisclosure referrin	e of written disclosure g to non-written disclosure (day:month year)